IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: All Cases	

PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO ABBVIE'S OMNIBUS MOTION IN LIMINE

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
Email: rjohnson@pschacter.com

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: cseeger@seegerweiss.com

Plaintiffs' Co-Lead Counsel *on behalf of* Plaintiffs' Steering Committee

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INTRODUCTION

AbbVie presents seventeen (17) separate motions *in limine*, which it divides into three categories of evidence: (1) so-called "historical" evidence (eleven motions); (2) expert testimony (two motions); and (3) case-specific facts in the *Konrad* and *Mitchell* cases (four motions). Plaintiffs do not concede the logic in that division. Nor do Plaintiffs concede the self-proving nature of the titles of AbbVie's motions or that the order of the motions in any way reflects the relative import of the evidence addressed. For the Court's ease, however, Plaintiff's respond *seriatim*, reciting AbbVie's motions exactly as it has cast them.

ARGUMENT

I. PLAINTIFFS' RESPONSES IN OPPOSITION ABBVIE'S MOTIONS *IN LIMINE* TO REGARDING "HISTORICAL EVIDENCE"

A. Evidence, Testimony and Argument Relating to Waived Claims

AbbVie recites four statements that it contends are "waived," apparently by virtue of Plaintiffs' argument in certain briefing to the Court, to wit, that: (1) "the FDA was misled"; (2) "information was withheld from FDA"; (3) "AndroGel should not have been approved"; and (4) "the AndroGel label was inadequate as approved." *See* AbbVie's Omnibus Motion *in Limine*, Doc. No. 1915 (hereinafter, "AbbVie's MIL"), at *1-2. AbbVie's motion is misplaced and deliberately misleading, and should be denied.

As Plaintiffs have made clear on numerous occasions, Plaintiffs do not purport to have legal *causes of action* that sound in any of the above. Indeed, Plaintiffs are not aware of federal or state law—common-law or otherwise—that would afford them such causes of action. Nor are Plaintiffs seeking to create a cause of action for violation of any federal law or regulation. But whether these targeted statements amount to cognizable legal claims and whether they might nonetheless be logical factual conclusions to be drawn from Plaintiffs' evidence are two entirely separate matters. Whatever can be said about the existence of a legal claim sounding in

"misleading the FDA," Plaintiffs have decidedly not waived their right to argue that factual conclusion insofar as the evidence they put forward on their common-law claims – including their claim for fraud on the Plaintiffs—supports it.[1]

Moreover, this Court has already explicitly rejected AbbVie's conceptualization of these matters. Indeed, remarkably, AbbVie alludes to the Court's comments in its own brief (although it conveniently does not quote them). *See* AbbVie's MIL, at *2. As the Court explained:

> AbbVie's main argument is that plaintiffs are intending to use Dr. Furberg's testimony to contend that the FDA should not have approved AndroGel because the clinical trials were inadequate to demonstrate its safety and efficacy. Plaintiffs say they are not challenging the FDA's approvals or to support a claim of fraud on the FDA, and the Court agrees that plaintiffs cannot advance claims along these lines. **But the testimony is properly admissible … to attempt to show that AbbVie and its predecessors conveyed misleading information to physicians and patients** concerning the safety and efficacy of the product. … This … is relevant and admissible to assist in establishing, among other things, that AbbVie made false representations regarding AndroGel.

See Case Management Order No. 48, Doc. No. 1897, at *43 (emphasis added).

B. Regulatory Activity and Changes to the AndroGel Label That Occurred After Plaintiffs Stopped Using AndroGel

AbbVie also seeks to exclude evidence of FDA regulatory activity that occurred after Plaintiffs stopped using AndroGel, which would include, among other things, evidence that, in 2015, FDA required AbbVie to add additional warnings to the AndroGel label. This motion should be denied in general as well as in particular as applied to the 2015 label change. Evidence of that label change is relevant and does not fall within the ambit of Rule 407 (Subsequent Remedial Measures).

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[1] It is particularly difficult to divine what AbbVie means when it says that Plaintiffs have waived any argument "that the AndroGel label was inadequate as approved." *See* AbbVie MIL, at *1-2. There is no dispute that the AndroGel package insert (PI) has always been FDA approved (until, in 2015, it was not and was thus changed). And one of the core claims of these cases is that the label was inadequate at all relevant times prior to Plaintiffs' injuries. It stands to reason that Plaintiffs factually challenge the "adequacy of the label as approved."

(footnote continues on next page)

Specifically, Plaintiffs request that the Court permit admission and use of the updated version of the AndroGel label that followed FDA's 2014 Advisory Committee hearing. *See* AndroGel PI, revised May 2015, attached hereto as Exhibit 1.[2] As the Court is aware, that hearing resulted in FDA requiring AbbVie and other TRT manufacturers to make a number of significant labeling changes, including, *inter alia*: addition of strengthened warnings relating to cardiovascular risk; addition of the qualifier that AndroGel has not been proven safe or effective for so-called "age-related hypogonadism" in the "Indications" section of the label; removal of the word "idiopathic" from the "Indications" section; and removal of symptoms discussion from the "Clinical Studies" section. *See* Letter from FDA to AbbVie, dated February 9, 2015, attached hereto as Exhibit 2.

1. The 2015 AndroGel Label Revisions Were FDA-Mandated and Thus Not Subject to Rule 407.

The subsequent remedial measure rule sets forth as follows:

> When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:
>
> • negligence;
>
> • culpable conduct;
>
> • a defect in a product or its design; or
>
> • a need for a warning or instruction.
>
> But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

Fed. R. Evid. 407.

But a measure undertaken by a party at the direction of a government authority falls outside the ambit of the "subsequent remedial measure" bar. *See, e.g.*, *Lolie v. Ohio Brass Co.*, 502 F.2d

[2] Plaintiffs refer collectively to the PI, which is for physicians, and the accompanying Medication Guide, which is for patients, as the AndroGel "label" or "labeling." *See* Exhibit 1 (including both PI and Medication Guide).

741 (7th Cir. 1974). In *Lolie*, the plaintiff sued the defendant coalmine owner alleging that a defective power cable had caused her husband's death while working in the mine. Following the incident, a state mine inspector directed the mine operator to add support to the cable, and the mine operator complied. The court observed that the measure should not have been excluded by the prohibition against subsequent remedial measures.[3] *Id.* at 744 ("Since the proffered evidence was relevant and there existed no valid policy reason for excluding it, the evidence was admissible.")

Other federal courts are in agreement. *See O'Dell v. Hercules, Inc.,* 904 F.2d 1194, 1204 (8th Cir.1990) ("An exception to Rule 407 is recognized for … remedial action mandated by superior governmental authority or undertaken by a third party because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence."); *Herndon v. Seven Bar Flying Service, Inc.*, 716 F.2d 1322, 1330-31 (10th Cir. 1983); *Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1343 (5th Cir. 1978); *Adams v. U.S., et al.*, 449 Fed. Appx. 653, 659-60 (9th Cir. 2011); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prod. Liab. Litig.*, 2011 WL 6740391, at *8 (S.D. Ill. Dec. 22, 2011); *In re Levaquin Prod. Liab. Litig.*, 2010 WL 4882595, at *1 (D. Minn., Nov. 24, 2010); *Bartlett v. Mutual Pharm. Co., Inc.*, 2010 WL 3092649, at *2-3 (D. N.H., Aug. 2, 2010); *see also Pau v. Yosemite Park and Curry Co.*, 928 F.2d 880, 888 (9th Cir.1991) (Rule 407 "applies only to a defendant's voluntary actions"). And Illinois courts, interpreting the Illinois Rules of Evidence, are in accord. *See Bulger v. Chicago Transit Auth.*, 801 N.E.2d 1127, 1134 (Ill. App. Ct. 2003) (collecting cases and holding that "[e]vidence of a defendant's post-accident remedial measures may be admitted where the defendant did not act voluntarily, but was required to act by an outside governmental authority.").

[3] The court's decision in *Lolie* pre-dated passage of Federal Rules of Evidence, and ultimately, the court found that the trial court's exclusion of the evidence in question was not error because it was "arguably cumulative." *Lolie*, 502 F.2d at 744. However, the court's reasoning stands as apt: the policy underlying the subsequent remedial measure bar had no applicability where the measure was undertaken by an entity other than the defendant. *Id.*

Of course, all of these courts are in line with the policy underlying the subsequent remedial measure rule, which is to avoid punishing actors who remedy dangerous conditions *on their own* and not to allow such remedies to be used as a sword against them in court. *See* Fed. R. Ev. 407, Advisory Committee Notes (1972) (rule rests on "social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety.")

Here, the 2015 revisions to the AndroGel label were made because of an explicit FDA requirement, set forth in the agency's February 2015 letter to AbbVie. The heading itself indicates the mandatory nature of the measures in question:

> **LABELING SUPPLEMENT AND PMR REQUIRED**
> **REMS MODIFICATION NOTIFICATION**

Exhibit 2, at 1 (emphasis in original). The body of the letter then lays out the agency's mandate for the strengthened warnings, starting, in relevant part, with:

> **SAFETY LABELING CHANGES**
>
> In accordance with section 505(o)(4) of the FDCA, we are notifying you that, based on the new safety information described above, in the published literature, and at the September 17, 2014, joint Advisory Committee meeting, the new safety information should be included in the labeling ….

See Exhibit 2, at 4 (emphasis in original). The agency further details those changes that were being required to the patient Medication Guide, as part of the company's Risk Evaluation and Mitigation Strategy (REMS) Requirement:

> **MEDICATION GUIDE**
>
> In addition to the changes described above, revise the Medication Guide to include the new safety information for Androgel 1%. Your revised Medication Guide will be considered part of the proposed REMS described below.

See Exhibit 2, at 7 (emphasis in original).

In short, the policy of Rule 407 has no applicability where, as here, the defendant does not voluntarily put the safety measure in place, but instead, is required to do it by a regulatory body. The policy is certainly not furthered where the need for the measure is made clear to that

government agency only after its own efforts to analyze underlying data and gauge the propriety of the measure. That is the reality of the 2015 AndroGel label revisions, and they are thus not barred by 407.

2. The 2015 AndroGel Label Revisions Are Relevant to Causation and Thus Not Subject to Rule 407.

Even assuming the 2015 label revisions could be considered AbbVie's (and not FDA's) remedial measures, they are nonetheless not subject to Rule 407 because they are probative on causation: both medical causation, *i.e.*, whether AndroGel can cause the injuries at bar; and proximate causation, *i.e.*, whether stronger warnings would have avoided the prescriptions, and hence the injuries, at bar.

Rule 407 excludes subsequent remedial measures only if they are offered for the purpose of attempting to prove "negligent" or "culpable conduct," enumerating certain exceptions (ownership, control, feasibility, and impeachment). But the list of exceptions is not meant to be exhaustive. *See Wetherill v. University of Chicago*, 565 F. Supp. 1553, 1558 (N.D. Ill. 1983); *see also Werner v. Upjohn Co.*, 628 F.2d 848, 856 (4th Cir. 1980) ("Plaintiff argues, and we agree, that the exceptions listed in Rule 407 [of] ownership, control or feasibility of precautionary measures (if controverted), and impeachment, are illustrative and not exhaustive."), *cert. denied*, 449 U.S. 1080 (1980).

Indeed, federal courts have recognized that, as used in Rule 407, the term "negligence" applies to culpability alone and not to every element of a negligence cause of action. Causation has always been a distinct concept. As the Fifth Circuit has acknowledged: "This court has long recognized that subsequent remedial measures can be introduced on the issue of causation if that is in controversy." *Brazos Rivers Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 429 (5th Cir. 2006); *see also Wetherill*, 565 F. Supp. at 1557 ("Because causation is analytically distinct from fault … it is

plainly 'another purpose' for which evidence of subsequent remedial measures can be offered under Rule 407.")

Here, that the 2015 label revisions are probative on causation demonstrates not only that they fall outside of Rule 407 but also that they will assist the jury in determining facts of consequence. First, AbbVie will argue, as a general matter, that AndroGel does not and cannot cause CV events. That is a factual matter wholly independent from AbbVie's culpability, and it is one on which the words of the 2015 label revisions are undeniably relevant. Namely, the 2015 label revisions required inclusion of a new warning section entitled "Cardiovascular Risk." *See* Exhibit 1, at Section 5.5 ("Cardiovascular Risk"). Similarly, the Medication Guide was revised to be direct in its discussion of the risk with patients:

> **ANDROGEL 1% can cause serious side effects including:**
>
> ***
>
> - **Possible increased risk of heart attack or stroke**

See Exhibit 1, at Medication Guide, at 29 (emphasis in original). AbbVie's position that AndroGel did not cause the injuries in *Konrad* and *Mitchell* makes the risk and causal language of the 2015 revisions relevant and admissible on that discreet issue. The very fact of inclusion of a warning for something like cardiovascular risk warning demonstrates the existence of "reasonable evidence of a causal association." *See* 201 CFR 201.57(c)(6).

The 2015 label revisions—and their impact on prescriptions—are also relevant to the question of proximate cause. Namely, a central question for these juries is whether stronger warnings would have avoided their injuries. *See, e.g.*, CMO 47, Doc. No. 1896, at *38. On that question, the jury should be permitted to consider whether the 2015 revisions changed Plaintiffs' physicians' prescribing practices.

In *Konrad*, the prescribing physician, Dr. Steven Overby, confirmed that: his current AndroGel prescribing practice and risk-benefit analysis takes into account the 2015 labeling

changes, *see* Excerpts of Deposition of Dr. Overby (Overby Dep.), attached hereto as Exhibit 3, at 127:18—129:12, and 134:1-4; the labeling revisions have had an effect on the amount of AndroGel scripts he writes, *see id.* at 131:7-10; today, he conveys the updated warnings to his patients, *see id.* at 129:9-12; his patients ultimately decide whether to accept AndroGel prescriptions, *see id.* at 134:10-19; and had he been aware of the warnings in 2010 he would have shared them with Plaintiff Konrad. *See id.* at 133:14—134:4, and 208:24—211:23.

The prescriber in *Mitchell*, Dr. Gordon Canzler, also gave clear testimony about his dependence on AndroGel labeling: "**I do depend mostly on the labeling**." *See* Excerpts of Deposition of Dr. Canzler (Canzler Dep.), attached hereto as Exhibit 4, at 159:21-22 (emphasis added). Dr. Canzler confirmed that, if he had been made aware of a warning for myocardial infarction and stroke back in 2007 when he initiated Plaintiff on AndroGel, he would have conveyed those risks to Plaintiff. *See id.* at 143:2-8.

The jury should also be permitted to consider evidence that the labeling changes decreased product prescriptions generally. AbbVie has admitted as much in internal company documents. In a May 13, 2015, email exchange enclosing an "AndroGel 1.62% Strategic Plan," the company acknowledged, *inter alia*:

> On March 3, 2015 the FDA announced that it will require manufacturers of prescription testosterone therapies to update product labeling by clarifying the approved uses of TRTs and adding information about a possible increased risk of heart attacks and strokes.

See AbbVie P1.0314, attached hereto as Exhibit 5, at ABBVIE-FST13810816. AbbVie then goes on to characterize FDA's labeling change requirements as a "paradigm shift" and notes that the TRT market has undergone "dynamic change" as a result, explaining:

> As a consequence, **the entire testosterone market has decelerated, with double digit declines** in the volume of both topicals and injectable TRTs.

Id. (emphasis added). AbbVie's own admissions that the 2015 labeling revisions impacted the TRT market is probative on the question of proximate causation. The jury should not be required

to contemplate that question entirely in the abstract, wondering whether the hypothetical testimony of prescribers is a good proxy for what they would actually do with actual stronger warnings. Instead, the Court should allow the jury to also weigh the fact that the label *did* change and that use *did* decline.

3. AbbVie's Presentation Will Open the Door to Admission of the 2015 AndroGel Label Revisions.

Rule 407 does not permit a party to hide behind the rule to prevent an adversary from responding to issues raised at trial. Thus, measures otherwise within the ambit of the rule are properly admitted where a defendant opens the door by, for instance, claiming that all "reasonable care" was being exercised at the time of the accident, *see Kenny v. SEPTA*, 581 F.2d 351, 356 (3d Cir. 1978) ("when the defendant opens up the issue by claiming that all reasonable care was being exercised at the time, then the plaintiff may attack that contention by showing later repairs which are inconsistent with it"); or discussing the product at issue in superlative terms. *See Muzyka v. Remington Arms. Co.*, 774 F.2d 1309, 1313 (5th Cir. 1985) (Rule 407 did not bar subsequent safety measure where excellence of alleged defective rifle was "core" of defense theory, from opening to closing).

Evidence or argument at trial that AndroGel is still on the market, FDA-approved, or recognized as safe and effective; or that physicians generally still prescribe AndroGel and that men still use it, directly implicate the present context and labeling for AndroGel. Allowing that argument without further qualification would be allowing the jury to hear a half-truth. The full truth is that the drug is indeed still FDA-approved and indeed still on the market, *but* with a stronger label containing the very types of warnings that Plaintiffs contend were missing until 2015. By way of example, the current label directly contradicts any argument or insinuation by AbbVie that AndroGel is now or ever was "safe and effective" for the broad, sprawling population

that was the target of its insidious marketing. *See* Exhibit 2, at 4 ("**Safety and efficacy** of Androgel 1% in men with age-related hypogonadism **have not been established**.") (emphasis added).

For all of the reasons discussed *supra*, the 2015 AndroGel label revisions are relevant and admissible and should not be excluded. Moreover, to the extent that this Court believes that the admissibility of the label change turns on whether AbbVie "opens the door," the subject is unsuitable for a motion *in limine* and should be addressed at trial.

C. Marketing and Promotional Materials Neither Seen Nor Relied upon by Plaintiffs Or Their Prescribing Physicians

AbbVie's motion seeks to exclude marketing materials "neither seen nor relied upon" by Plaintiffs or their physicians, and it fails for two independent reasons. First, the motion wholly ignores the mountain of marketing evidence to which Plaintiffs' and their physicians *were* exposed. Second, the motion ignores the Court's extensive discussion about the general relevance of marketing and promotional conduct in its denial of summary judgment on "off-label" issues. *See generally* CMO No. 48, Doc. No. 1897. The motion should be denied.

1. Marketing Evidence in Konrad

In *Konrad*, Plaintiff has been consistent since the commencement of his lawsuit that he saw AbbVie advertising relating to TRT. *See* Konrad Plaintiff Fact Sheet (PFS), attached hereto as Exhibit 6, at Section VII, N. and N.1. During his deposition, Plaintiff confirmed his direct exposure to specific aspects of AbbVie's marketing. *See* Excerpts of Deposition of Plaintiff Konrad (Konrad Dep.), attached as Exhibit 7, at 124:2-10, 125:15-25, 126:11—127:13, 190:7-16, 208:11-14, 209:1-3, 216:8-14, and 218:10—219:8. Plaintiff's prescriber, Dr. Overby, similarly confirmed his exposure to both AbbVie sales representatives and the materials they would provide to him. *See* Ex. 3 at 100:20—101:1, 115:11-22, 117:10-11, and 122:18-23. And one of the AbbVie sales representatives who called on Dr. Overby, Jennie Fields, testified at great length concerning the marketing messages and materials she delivered to Dr. Overby. *See* Excerpts of Deposition of

Jennie Fields (Fields Dep.), attached hereto as Exhibit 8, at 52:3-6, 52:14-16, 61:15—62:15, 68:16—69:21, 172:20-25, 190:19—191:6, 193:2-8, 197:24—198:23, 212:4-19, and 224:11-25.

Making absolutely no mention of Dr. Overby's or Ms. Fields' testimony, AbbVie summarily concludes that "Plaintiffs' prescribing physicians did not rely upon [marketing] when they wrote Plaintiffs' AndroGel prescriptions." AbbVie MIL, at *10. That sweeping and unsupported claim is directly contradicted by this Court's findings that "[e]ach of the physicians testified regarding 'low T' marketing efforts by AbbVie sales representatives, and a reasonable jury could find in each instance that AbbVie's marketing of the drug for age-related hypogonadism or other non-indicated uses was a substantial factor in the prescribing decision." CMO No. 48, Doc. No. 1897, at *19.

And while AbbVie dismisses Plaintiff's exposure as merely having seen a "single shadow," *see* AbbVie MIL, at *8, that argument is fairly disingenuous. Indeed, Plaintiff's memory of the "shadow" is not at all insignificant, as the shadow was the defining feature of that particular advertising campaign. Plaintiff confirmed recognition of these "shadow" campaign video advertisements during his deposition, *see* Konrad Dep., at 216:3-10, and he also identified the "AndroGel Patient Support and Savings Program" pamphlet he received at the time of his initial prescription. *See* Konrad Dep. at 190:7-12; *see* AndroGel Pamphlet, attached hereto as Exhibit 9.

In short, all of the materials testified to by Plaintiff, his physician, and AbbVie's sales representative have a direct and undeniable connection to his individual case, and are relevant and admissible for that reason alone.

2. Marketing Evidence in Mitchell

The marketing evidence in *Mitchell* is likewise extensive. Plaintiff's prescriber, Dr. Canzler, testified extensively to his exposure to the Defendants' marketing materials. *See* Ex. 4 at 104:16-21, 105:5—106:18, 107:2-13, 108:7-15, 109:12—110:3, 122:24—123:2, 128:3-13, and 139:2-6. And the AbbVie sales representatives who called on Dr. Canzler, Pamela Peet and Julia

Adams, testified to the messages and materials they delivered. *See* Excerpts of Transcript of Pamela Peet (Peet Dep.), attached as Exhibit 11, at 67:13-15, 68:13—69:21 , 78:22—79:14, 80:18-21, 86:9-18, 175:1-16, 175:24—176:2, 176:22—177:2, 177:9-23; and Excerpts of Deposition of Julia Adams (Adams Dep.), attached as Exhibit 12 at 27:14-17, 35:8-22, 109:4—110:12, 119:3-24, 148:7—149:5.

As in *Konrad*, all of the materials testified to by Mr. Mitchell's physician, and AbbVie's sales representative have a direct and undeniable connection to his individual case and should not be excluded.

3. *Marketing Evidence Generally*

Putting aside all of the direct marketing links in each individual case, AbbVie's motion fails insofar as it essentially attempts to re-litigate the "off-label" summary judgment motion that the Court has already denied. *See generally* CMO No. 48, Doc. 1897. Throughout that opinion and order, this Court repeatedly acknowledged the general relevance of AbbVie's marketing evidence. Without reciting all of the Court's commentary here, the Court held, in relevant part:

> Plaintiffs here have presented evidence sufficient to permit a reasonable jury to find that AbbVie had knowledge that its advertisements contained false or misleading statements. AbbVie was told on several occasions that AndroGel was not an appropriate treatment for age-related low testosterone.
>
> ****
>
> AbbVie's strategy for advertising AndroGel to primary care physicians, specifically, was to "sell marketing expansion first and AndroGel second." … AbbVie launched a "disease awareness" advertising campaign for men with low testosterone levels. It distributed direct-to-consumer advertisements through unbranded websites, third parties, and television advertisements, encouraging men to request that their healthcare professionals test them for "low T."
>
> This and other evidence would permit a reasonable jury to find that AbbVie acted willfully and wantonly, thus permitting an award of punitive damages.

Id. at *24-25; *see also In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6812683, at *2–3 (S.D. Ill. Dec. 27, 2011) (finding off label use and marketing relevant issues for jury).

Based on all of the case-specific evidence of marketing and promotional influence, and in view of the Court's summary judgment orders setting forth the relevance of AbbVie's extensive marketing and promotion generally, this motion should be denied. The evidence in question is undeniably relevant.

D. Other Drugs and Other Manufacturers

AbbVie moves broadly to exclude evidence of "other drugs and other manufacturers." The motion should be denied.

First, insofar as AbbVie's motion is couched in such a broad and vague way, the motion necessarily fails from the start. *See* CMO No. 48, Doc. No. 1897, at *35 ("Perfunctory arguments are forfeited."). Plaintiffs do not concede in any way that as-yet-unidentified documents or testimony which arguably could fall under the umbrella of the motion's title are either not relevant or unfairly prejudicial under Rule 403. The motion, as titled, should be denied as premature.[4]

Second, the motion should be denied in substance as to the three specific topics that AbbVie identifies because the evidence in question is relevant. *See* AbbVie MIL, at *11. Plaintiffs take those areas *seriatim*.

1. The Depakote Corporate Integrity Agreement (CIA)

It is true that AbbVie's misconduct, relating to its prescription drug Depakote, is not at issue in these cases. It is also true that the details of the civil and criminal investigations of that

[4] By way of example, AbbVie caps this motion by alluding to—but not identifying—certain "other-company documents" used at the depositions of three former Endo employees and one current Lilly employee, which also appear on Plaintiffs' Exhibit List. *See* AbbVie MIL, at *14, n. 4. This lack of clarity as to the potential universe of documents covered by its motion underscores its prematurity.

misconduct are not at issue. But it is equally true that AbbVie might put such evidence into issue by raising and arguing "good company" conduct to the jury. Plaintiffs have moved to exclude such "good company" conduct, *see* Plaintiff's Omnibus Motion *in Limine* (Plaintiffs' MIL), Doc. No. 1913, at *8, but in the event that the Court denies Plaintiffs' motion and/or AbbVie argues "good company" conduct outside of TRT, its *misconduct* decidedly becomes relevant.

Separately, the CIA itself is relevant for an independent purpose that AbbVie's motion ignores. The CIA embodies a voluntary agreement between the Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS) and Abbott and its successors (eventually, Abbott Laboratories and AbbVie). *See* Corporate Integrity Agreement (CIA), attached hereto as Exhibit 13 at 1-2. Although AbbVie characterizes the agreement as the "Depakote CIA," it is, in fact, not specific to Depakote. Instead, the agreement covers *all* of Abbott's pharmaceutical products. *See id.* at 4. It outlines Abbott's (and by extension AbbVie's) agreement to be bound by standards relating to myriad company affairs, including the very sorts of conduct that will be at issue in these trials: promotional activities generally, *see, e.g.*, *id.* at 4,15; training for improper versus proper promotional activities, *see id.* at 18; requirements for speaker programs, *see id.* at 29; and close observation of sales representatives for the purpose of "**identification of any potential off-label promotional activity or other improper conduct by the sales representative**." *Id.* at 30 (emphasis added).

These agreed requirements go above and beyond those standards to which AbbVie would ordinarily adhere. Indeed, the CIA is a concession that AbbVie saw the need to do so and accepted the terms of those heightened requirements.

2. Evidence Relating to Dihydrotestosterone (DHT)

By way of background, DHT is an endogenous androgen and a major active metabolite of testosterone. The Court need not look any further than the AndroGel label for confirmation of that basic information. *See* Exhibit 1 at Sections 12.1 (Mechanism of Action) and 12.3

(Pharmacokinetics). Plaintiffs' scientific experts have observed this biological reality in their reports and might have occasion to explain it at trial. Accordingly, insofar as DHT is a fundamental and unavoidable part of the story of male testosterone and how it functions, the Court cannot possibly exclude evidence of DHT generally.

Under this category, AbbVie's motion appears to takes aim at evidence relating to its abandoned DHT-based product. But some of that evidence is also fundamentally relevant to AndroGel. Specifically, in the mid- to late-1990s, AbbVie's predecessor was communicating with FDA about what would be required for approval of an application to market the DHT product, but the application was never pursued. Among FDA's concerns were the need to study DHT in older men. *See* March 11, 1997 Memorandum, P1.2012, attached hereto as Exhibit 14 at 2. That the company elected not to do so is probative on the question of its liability in embarking on a campaign to market to that population, even in the absence of a study it could have undertaken as early as the late 1990s.

3. TRT Marketing Communications Between FDA and Other Manufacturers

As the Court has observed, "a reasonable jury could infer that AbbVie promoted AndroGel for the treatment of a condition referred to as 'Low T,' knowing that AndroGel had no cognizable benefits for this class of patients." CMO No. 47, Doc. No. 1896, at *53. Likewise, "a reasonable jury could find AbbVie liable for making misrepresentations about the safety and efficacy of AndroGel for treating age-related hypogonadism or for making misrepresentations about the indications for which the FDA approved AndroGel." CMO No. 48, Doc. No. 1897, at *16. And "AbbVie's strategy for advertising AndroGel to primary care physicians, specifically, was to 'sell market expansion first, and AndroGel second'." *Id.* at *24.

But AbbVie's marketing strategy and efforts were not unique to AbbVie. Indeed, as MDL Plaintiffs have alleged vis-à-vis all MDL Defendants who operated in the TRT marketplace, market expansion was a universal goal and direct-to-consumer advertising and off-label promotion

were common means to that end. If AbbVie knew of FDA communications with other manufacturers relating to the impropriety of TRT marketing messages that were similar to its own, that evidence is relevant to notice. That AbbVie would ignore that notice and market improperly in spite of FDA admonition is only further evidence of culpability and conduct warranting punitive damages. *See generally* CMO Nos. 47 and 48, Doc. Nos. 1896 and 1897.

Interestingly, AbbVie's MIL preemptively and correctly points out "notice" as a relevant purpose and then dismisses that purpose as "beguilingly simplistic." AbbVie MIL, at *13. In fact, what is beguiling is AbbVie's misleading argument. AbbVie claims that this type of evidence "relate[s] to periods of time that are remote from the prescriptions at issue" and "Plaintiffs have all of the other manufacturers' documents. AbbVie does not." *Id.* But the example AbbVie provides directly contradicts both of those statements. Indeed, AbbVie points to an FDA "Warning Letter" sent to Slate Pharmaceuticals concerning marketing violations relating to its TRT product, Testopel. *See* FDA Letter to Slate (Slate Letter), attached hereto as Exhibit 15. The letter is dated March 24, 2010, and it details the improprieties of Slate's TRT marketing efforts, which were parallel to AbbVie's. In other words, that letter was sent to Slate *while* Plaintiff Mitchell was using AndroGel and just a little over one month *before* Plaintiff Konrad began using AndroGel. And the letter certainly was not hidden from AbbVie's eyes. The copy of the Slate letter on Plaintiffs' exhibit list was produced to Plaintiffs *by AbbVie* and bears AbbVie's BATES stamping. *See id*.

In short, FDA communications with other drug companies relating to the age-related and symptom-driven marketing for other TRT products is chargeable against AbbVie as notice, so long as there is foundation to demonstrate (as with the Slate Letter) that AbbVie became aware of it.

E. Evidence, Testimony, and Argument Regarding Unofficial Statements by FDA Employees

Like its motion on "other drugs and other manufacturers," AbbVie's motion to exclude "unofficial statements by FDA employees" is impossibly broad and vague and thus fails as premature.

Insofar as the body of the motion targets "unofficial public statements by former FDA employee Dr. Daniel Shames," the motion should be denied. Dr. Shames' statements are relevant, not unfairly prejudicial, and have been properly relied upon by Plaintiffs' regulatory experts, Drs. David Kessler and Peggy Pence, in forming their opinions. Indeed, both experts have relied upon a number of statements by Dr. Shames and communications from Dr. Shames to AbbVie, which go to the company's notice of the need to conduct further studies and its over-promotion of AndroGel. *See* Excerpts of Report of Dr. Kessler (Kessler Report), attached hereto as Exhibit 16; and Excerpts of Report of Dr. Pence (Pence Report), attached hereto as Exhibit 17. This Court has already denied AbbVie's multi-pronged *Daubert* attacks on both experts, explaining why these experts' opinions are relevant for the jury's consideration. *See* CMO No. 48, Doc. No. 1897, at *29-36.

Furthermore, although AbbVie dismissively casts Dr. Shames' statements as merely "a series of articles and opinion pieces in the mainstream media" and in "broadcast interviews," that characterization is not accurate. Just one example is a May 2007 internal company email, which discussed and attached a presentation by Dr. Shames in his capacity as Deputy Director of FDA's Office of Drug Evaluation, entitled "Regulatory Challenges Testosterone Therapy in Aging Males." *See* May 2007 Email and Shames Presentation, attached hereto as Exhibit 18. That presentation is decidedly more than a mere "opinion in the mainstream media," and AbbVie comments that Dr. Shames' presentation discussed, *inter alia*, some data potentially linking TRT to "increased CV morbidity." *Id.*

As to AbbVie's general hearsay objection to all Shames' statements, it is impossible to respond in any meaningful way without knowing exactly which statements or documents AbbVie is actually attacking. But as a general matter, any statement by Dr. Shames is properly admissible, in the first instance, not for the truth of the matter asserted but for purposes of notice and the fact that it was uttered. *See* Fed. R. Evid. 801. Additionally, the statements by Dr. Shames satisfy various hearsay exceptions, and Plaintiffs can articulate any such additional grounds whenever AbbVie actually objects to specified materials.

F. Evidence, Testimony and Argument Regarding Foreign Regulatory Actions and Labeling

Here, AbbVie seeks to exclude evidence of foreign labels and foreign regulatory action, again, couching its attack in immeasurably broad terms but actually pointing to only two exhibits. *See* AbbVie MIL, at *15 (citing Plaintiffs' Exhibits 48, and 565). The motion should be denied.

The exhibits cited by AbbVie concern its interactions with Health Canada, Canada's drug regulatory agency. By way of example, in 2005 Health Canada had communications with Solvay (one of AbbVie's predecessor entities) relating to proposed "class labeling," *see* March 2006 Email and attached Canadian Class Labeling Meeting Minutes, attached hereto as Exhibit 19. Just as with much of the evidence AbbVie challenges in its motion, its interactions and communications with Health Canada go to notice and culpability: notice of issues relating to the need to conduct further study of AndroGel and potential safety signals linking the drug to risks. These are relevant and admissible, and the motion should be denied.

G. The Wealth, Profits, or Employee Compensation of AbbVie

AbbVie seeks to exclude evidence of its wealth and profits and its employees' compensation, arguing that these are not relevant matters and in any event would be unfairly prejudicial under Rule 403. The motion should be denied.

First, this Court has already determined that a jury could find AbbVie liable for punitive damages under Illinois law. CMO. No. 47, Doc. No. 1896, at *53. And the Court has observed that, "[u]nder Illinois law, 'evidence of net worth is . . . the preferred method of assessing punitive damages'." *See* CMO. No. 49, Doc. No. 1898, at *1-2 (quoting *Cent. Bank—Granite City v. Ziaee*, 544 N.E.2d 1121, 1127 (1989)). That observation is, of course, consistent with both Supreme Court jurisprudence, *see Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22 (1991) (affirming Alabama Supreme Court's articulation of punitive factors, including "(c) the profitability to the defendant of the wrongful conduct and the desirability of removing that profit and of having the defendant also sustain a loss; (d) the 'financial position' of the defendant …"); and *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 464 (1993), and Illinois jurisprudence. *See Proctor v. Davis*, 682 N.E.2d 1203, 1216 (Ill. 1997); and *E.J. McKernan Co. v. Gregory*, 623 N.E.2d 981, 997 (Ill. App. 1993) ("The relevant circumstances in reviewing an award of punitive damages include 'the nature and enormity of the wrong, the financial status of the defendant, and the potential liability of the defendant'.").

But AbbVie claims otherwise, pointing to a non-controlling case from the Southern District of Indiana interpreting Seventh Circuit jurisprudence. *See* AbbVie MIL, at *18 (relying on *Yund v. Covington Foods, Inc.*, 193 F.R.D. 582, 586-87 (S.D. Ind. 2000) (citing *Zazu Designs v. L'Oreal, S.A.*, 979 F.2d 499, 508 (7th Cir. 1992)). AbbVie is wrong and appears to have deliberately avoided citing more recent cases on this point.

Indeed, courts in this district have expressly declined to follow the reasoning of *Yand* or the dicta in *Zazu*, instead adhering to the well-settled principle that a defendant's wealth or financial position is an appropriate factor for a jury to consider in deliberating on punitive damages. *See Isbell v. Crane*, 74 F. Supp. 3d 898, 899 (N.D. Ill. 2014) (citing *Leister v. Dovetail, Inc.*, 546 F.3d 875, 883 (7th Cir. 2008)); *Aqua Dots Products Liability Litigation*, 270 F.R.D. 322, 325 (N.D.

Ill. 2010) ("More recent cases in this district … have dismissed this portion of *Zazu Designs* as dicta."); *Jones v. Scientific Colors, Inc.* 2001 WL 902778, at *1 (N.D. Ill. 2001) (rejecting contention that controlling precedent of Seventh Circuit bars consideration of defendant's wealth for purposes of punitive damages); and *EEOC v. Staffing Network, L.L.C.*, 2002 WL 31473840, at *1 (N.D. Ill. 2002) (same). In short, AbbVie's wealth—including income, revenue, profits, sales, and budgets for research, marketing, and/or sales—is relevant and admissible.

Second, any AbbVie employee who takes the stand or testifies by way of prior deposition—indeed any witness at all who testifies—is subject to cross examination on bias and credibility. The amount of AbbVie's employees' compensation is relevant on those points. *See In re: Tylenol,* 181 F. Supp. 3d 278, 294 (E.D. Pa. 2016) ("A witness's possible bias created by certain compensation structures would relate to actions taken while the witness was employed with the defendants. While his or her current compensation at a different job may not be relevant, previous **compensation while working for the defendants may be relevant to their motivation for making certain decisions** on behalf of the defendant corporations.") (emphasis added); *see also Charlton v. Wells Fargo Bank, N.A.*, 2016 WL 7338527, at *6 (D. N.J. Dec. 19, 2016).

H. General Criticisms of the FDA That Are Not Tied to the Facts at Issue

Respectfully, this motion appears moot. AbbVie objects to a category of testimony, at least insofar as Dr. Pence is concerned, that the Court appears clearly to have excluded by virtue of its "off-label" opinion and order. *See* CMO No. 48, Doc. No. 1897, at *35-36 (holding that Dr. Pence may not testify as to *why* FDA acted or did not act with respect to AndroGel promotional materials). However, to be clear, Plaintiffs do not concede that evidence of FDA's insufficient resources and inability to effectively enforce its own rules should be excluded. Instead, Plaintiffs preserve their right to make a proffer for the evidence at trial (including the IOM report), especially to address any argument or evidence by AbbVie relating to FDA actions and inactions—in particular, argument or evidence attempting to shift responsibility for the content of AndroGel's

post-approval label to FDA, or reliance on inaction by FDA as evidence of approval of AbbVie's conduct.

I. Prescriber Misconduct

AbbVie seeks to exclude what it calls "prescriber misconduct," which is a proposition that has facial appeal. But the evidence AbbVie is really driving at here pertains to the influence and success of *its own* far-reaching and well-orchestrated marketing efforts. The motion should be denied as the evidence in question is relevant.

The evidence AbbVie points to is in the form of "men's clinics" offering TRT and overly superlative statements by those in the medical community concerning the benefits of TRT. *See* AbbVie MIL, at *20-22. But this kind of evidence is the direct outgrowth of AbbVie's marketing, and should be permitted to demonstrate the efficacy of the money and resources it spent in the furtherance of "sell[ing] market expansion first, and AndroGel second." CMO No. 48, Doc. No. 1897, at *24. In short, the evidence in question is relevant and admissible, even if it did—indeed, especially *because* it did—create an unduly expanded view of "low T" and treatable conditions in the medical community (that was, of course, AbbVie's very goal).[5]

J. Argument That AbbVie "Bought the Doctors"

AbbVie moves to preclude Plaintiffs from using the phrase "AbbVie bought the doctors." The motion should be denied as argued.

On its face, AbbVie's motion appears to be a challenge *solely* to use of the verbatim phrase "bought the doctors" and not to the admissibility of evidence that might support that inference.

[5] As to physician conduct, Plaintiffs have brought their own motion *in limine* to preclude argument suggesting that any physician in either case committed malpractice or otherwise fell below some applicable standard of care. *See* Plaintiffs' MIL, Doc. No. 1913, at *10. Without a standard of care expert, any such argument or opinion testimony in that area is improper. So, insofar as claimed "prescriber misconduct" could be construed to cover that area, Plaintiffs do not disagree with the concept. However, as explained in text, AbbVie's marketing influence on physicians is admissible.

See AbbVie MIL, at *21 ("[a]rguing that doctors had a financial interest is one thing …"). There is extensive record evidence that AbbVie paid consulting fees to physicians and Key Opinion Leaders (KOLs) and sponsored medical education conferences. Insofar as the motion, like most of AbbVie's other motions, is not tethered to identifiable evidence, the motion should be rejected out of hand. Evidence of payments by AbbVie to physicians or entities in the medical community to influence the TRT market are relevant as they bear on AbbVie's mind state and physicians' bias.

Furthermore, as to AbbVie's complaint about the phrase "bought the doctors," it points to no authority—evidentiary or otherwise—as support for preclusion of such an argument. If the evidence presented to the jury supports it, there is no reason that such an argument cannot be pursued. The motion should be denied.

K. Requirement That Plaintiffs Establish Through a Reliable Fact Witness How Documents Are Relevant Where Their Context is Unclear

Although slightly repackaged here, this Court has twice rejected AbbVie's argument that document "sponsors" are necessary. AbbVie's attempted third bite at the apple should also be denied.

AbbVie first raised this challenge during the Court's Case Management Conference (CMC) on April 26, 2017. Specifically, AbbVie counsel took the position that Dr. Kessler should be forbidden from walking through the "history" of AndroGel and the FDA with "many documents," insisting instead that documents need a proper "sponsor." *See* Excerpts of Hearing Transcript, dated April 26, 2017, attached hereto as Exhibit 20 at 19:12-14. This Court disagreed: "There is no rule, I defy you to find one, that says documents have to have, as you use the term, sponsors. They don't." *Id.* at 20:18-20. Instead, the Court advised AbbVie to attack such testimony through traditional cross-examination or presentation of their own evidence. *Id.* at 20: 21-25.

AbbVie raised this argument for the second time in its summary judgment challenge to "off label" claims and accompanying expert attacks, including a request to exclude Dr. Kessler's "anticipated testimony on the history of AndroGel's promotional materials and its dealings with the FDA." *See* CMO No. 48, Doc. No. 1897, at *33. The Court again rejected AbbVie's argument:

> [T]o the extent [Dr. Kessler] is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials. AbbVie will have a full and fair opportunity to address any claims of incompleteness or undue emphasis during cross-examination and presentation of contrary evidence.

Id. at *33; *see also id.* at *35 (rejecting same argument as to Dr. Pence).

Although AbbVie's instant motion avoids any mention of Plaintiffs' regulatory experts, the grist of its argument gives away the fact that this is its third bite at the apple. *See* AbbVie MIL at *21-22 ("AbbVie's main concern is about the introduction of a large number of exhibits through the testimony of experts who lack the personal knowledge and competence to establish the factual predicates for relevance."). For the same reasons the Court has already rejected this argument, it should deny the instant motion as well.

II. PLAINTIFFS' RESPONSES IN OPPOSITION ABBVIE'S MOTIONS *IN LIMINE* TO REGARDING EXPERT TESTIMONY

A. Barring Plaintiffs from Converting Expert Deposition Testimony into Fact Testimony to Be Used at Trial

AbbVie seeks to exclude certain deposition testimony of its own experts. Couched as a challenge to fairness, AbbVie's contention instead boils down to a feigned cry that it has somehow been outsmarted by Plaintiffs in the way they cross-examined AbbVie's experts during sworn deposition. The motion has absolutely no support in the law and should be rejected out of hand.

As a threshold matter, it is a truism that a party may not elevate a fact witness to an expert witness without following the expert disclosure rules and subjecting that witness to *Daubert*

scrutiny. *See Musser v. Gentiva Health Sys.*, 356 F.3d 751, 757 (7th Cir. 2004). Indeed, expert disclosure requirements are above and beyond those of mere fact witnesses, and there can be little dispute on that point.[6] *See id.*; *and see* Fed. R. Civ. P. 26(a)(2)(A).

But AbbVie has fashioned a converse and novel legal proposition here: that a party should not be permitted to "convert expert deposition testimony into fact testimony." AbbVie MIL, at *25. The proposition is hard to understand on its face, and AbbVie points to no authority for it.

AbbVie does not claim (nor could it), that Plaintiffs violated the rules of procedure or any of the Court's rules or deadlines relating to taking its experts' depositions. Nor does its motion claim that any of Plaintiffs' questioning was improper. Indeed, beyond the description that the deposition testimony in question was "extensive" and based on "facts known by the experts personally," AbbVie fails to identify any of the testimony that it contends would run afoul of its new rule. Instead, at bottom, AbbVie's protests are simply that while defending these depositions, it did so "without care to assure that the factual record [was] complete and accurate." AbbVie MIL, at *25-26.

In short, this odd motion should be denied. Plaintiffs properly deposed AbbVie's experts. AbbVie defended them. Their deposition testimony is now admissible at trial insofar as it is relevant and otherwise admissible under the Rule of Evidence.

B. Barring Plaintiffs' Experts from Providing Opinions Not Timely Disclosed

AbbVie contends that it was "sandbagged" by certain of Plaintiffs' supplemental expert materials, including supplemental reports by Drs. Gerstman and Ardehali, served on April 25, 2017, supplemental lists of materials considered by Drs. Gerstman, Ardehali, Cuculich, Pence and

[6] As addressed in Plaintiffs' MIL, at *6-8, this is precisely why AbbVie's desire to have its fact witnesses give expert testimony at trial is improper and should not be countenanced. There is thick irony in AbbVie's attempt to flout the expert disclosure rules relating to its fact witnesses, while at the same time conjuring a converse rule to protect its experts from cross examination. Clever to be sure. But not supported by any evidentiary or procedural rule.

Kessler, served on May 5, 2017. *See* Gerstman Supplemental Report (Gerstman Supp.), attached hereto as Exhibit 21; Ardehali Supplemental Report (Ardehali Supp.), attached hereto as Exhibit 22; Materials Considered by Gerstman (Gerstman Materials), attached hereto as Exhibit 23; Materials Considered by Ardehali (Ardehali Materials), attached hereto as Exhibit 24; Materials Considered by Cuculich (Cuculich Materials), attached hereto as Exhibit 25; Materials Considered by Pence (Pence Materials), attached hereto as Exhibit 26; and Materials Considered by Kessler (Kessler Materials), attached hereto as Exhibit 27. AbbVie seeks relief in the form of limitations on these experts' testimony at trial. But these materials were timely, proper, and no different in nature than AbbVie's own supplemental expert reports. In any event, the materials pose absolutely no prejudice to AbbVie. Accordingly, and as explained in detail below, the motion should be denied.

First, all of the challenged supplements were timely served under CMO No. 36, Doc. No. 1618, and Rule 26(e). In CMO No. 36, the Court specifically anticipated that the parties would file supplemental expert disclosures *and* gave the parties directions for the timing of these disclosures for these bellwether cases. *See* CMO 36, at *3, ¶ 5. Specifically, the Court ordered that "(a)ny supplementation of a party's Rule 26(a) (2) disclosures must be done in accordance with and by the time limitation specified in Rule 26(e)." *Id.* According to Rule 26 (e), supplements were due on the May 11, 2017, deadline set by the Court's March 24, 2017 Minute Order for filing the "final pretrial order." *See* Doc No. 1814. As AbbVie's motion concedes, ***all*** of the materials it challenges here were served on or before May 5, 2017. *See* AbbVie MIL, at *26.

While all of plaintiffs' supplemental expert disclosures were timely, one of AbbVIe's "timeliness" challenge in particular deserves special attention, *i.e.*, the attack on Dr. Gerstman's April 2017 supplemental report. Specifically, AbbVie challenges that supplement because it came

allegedly too late after the publication of several studies published a month or two earlier, in February and March 2017. *See* AbbVie MIL, at *28. In essence, AbbVie claims that Dr. Gerstman did not "write fast enough." That argument is facially disingenuous and flies in the face of logic and CMO No. 36. At bottom, none of Plaintiffs' supplemental expert disclosures—including Dr. Gerstman's—was untimely.

Second, and contrary to AbbVie's contention, Plaintiffs' supplemental disclosures were proper "additions or changes" pursuant to Rule 26(e). Even a cursory review of these materials make that clear.

Most of the materials identified in Plaintiffs' May 5, 2017 "supplemental materials considered" lists for Drs. Cuculich, Ardelali, Gerstman Kessler and Pence are late-2016 and 2017 studies which were not available prior to the November 1, 2016 expert disclosure deadline. Also included in these supplemental materials considered were: AbbVie's own expert reports, which were served on December 6, 2016; transcripts of the depositions of AbbVie's experts' and other witnesses who were not deposed until after November 2016; and medical records and documents obtained and collected late in 2016. These materials include documents from AbbVie's eleventh-hour production, for example, FIOA documents (served on the PSC in December 2016) and certain of AbbVie's AER backup files also produced to the PSC in late 2016. In several other instances, pre-2017 references were, in fact, duplicative of previously disclosed references contained in other earlier submissions by those same experts. C*ompare* Gerstman Materials (Ex. 24) *with* Gerstman "Response Report" (Dec. 26, 2016), attached hereto as Exhibit 28; *compare* Ardehali Materials (Ex. 24) *with* Ardehali Supp. (Ex. 22).

Third, and to illustrate that AbbVie's "timeliness" argument wholly lacks merit, AbbVie served *its own* supplemental disclosures before May 11, 2017. For example, it produced a March 8 report of Dr. Baillargeon. *See* Baillargeon Supplemental Report (Baillargeon Supp.), attached

hereto as Exhibit 29. That report contains sixteen references, including references from 2014 and 2016, which were not in his initial report. *Id.* Similarly, Dr. Khera produced two additional supplemental disclosures—one on March 8 and another on May 5. *See* Khera Supplemental Reports (Khera Supp.), collectively attached hereto as Exhibit 30. While both of Dr. Khera's supplemental disclosures do not list the additional materials relied on, one can glean that he relies on both "recent" and older materials. Finally, Dr. French produced a supplement dated May 6, 2017, which contained his additional review of materials relating to Plaintiff Konrad. *See* French Supplemental Report (French Supp.), attached hereto as Exhibit 31.

Finally, AbbVie was neither surprised nor prejudiced by these materials. Each of the Plaintiffs' experts in question considered the additional studies or documents and incorporated the data into their overall opinions, with each expert noting that their respective opinions have not changed. Moreover, the additional materials considered were supportive of, but did not change, Dr. Pence's and Kessler's opinions (which were not causation opinions). Rule 26(e) requires notification of "additions and changes." That is exactly what plaintiffs did. There is no surprise. There is no prejudice. The motion should be denied.

III. PLAINTIFF'S RESPONSES IN OPPOSITION TO ABBVIE'S MOTIONS *IN LIMINE* TO REGARDING *KONRAD* AND *MITCHELL* SPECIFICALLY

A. Evidence Relating to Erectile Dysfunction, Diabetes, HIV, and Any Other Conditions That Plaintiffs Konrad and Mitchell Did Not Have

AbbVie seeks to exclude "evidence relating to" a variety of conditions and symptoms contending that Plaintiffs did not suffer from them. First, yet again, the motion is broad and vague and fails to target any actual evidence. It fails for that reason alone. Second, the motion might well be a thin guise to make inroads on the marketing and promotional efforts of AbbVie relating to those conditions. If so, as set forth extensively *supra*, in the Court's order on "off-label" marketing, and in Plaintiffs' expert reports, AbbVie's conduct in market expansion is relevant and admissible, as they Court has already held. The motion should be denied.

B. The Term "Widow Maker"

AbbVie claims that the term "widow maker," which refers to the particular type of heart attack suffered by Plaintiff Konrad, should be excluded as unfairly prejudicial. But the danger of the term's unfair prejudice does not *substantially* outweigh its probative value. *See* Fed. R. Evid. 403. Instead, the term is probative to convey the potential severity of the injury that AndroGel caused in this particular case. At least one trial court has denied a similar request to exclude the term as unfairly prejudicial. *See Trattler v. Citron*, 2004 WL 5649070 (D. Colo. Aug. 18, 2004). This Court should deny the motion as well.

C. Evidence Relating to Unavailable Remedies

1. Plaintiff Konrad's Children

AbbVie seeks to limit the testimony of Plaintiff Konrad's children. The motion should be denied. There is no dispute that Plaintiff Konrad's children do not have independent claims for loss of parental consortium in this case. However, and importantly, their testimony is relevant and probative as to Plaintiff's damages, pain and suffering. *See. e.g., Rogers v. Louisville Land Co.*, 367 S.W. 3d 196, 209-10 (Tenn. 2010). As close-up observers, they are able to provide first-hand testimony of how Mr. Konrad's life has been changed by his heart attack. Any conceivable prejudice does not substantially outweigh the probative value of such testimony, which will allow the jury to understand the effect that Plaintiff's heart attack had on him and his life. A blanket pre-trial ruling limiting future testimony of Plaintiff's children, who are proper fact witnesses, is premature.

2. Evidence of Lost Income by Plaintiff Mitchell's Wife

Plaintiff does not oppose this motion.

3. Profit Disgorgement

Plaintiffs do not oppose this motion.

4. Pain and Suffering

AbbVie's motion seeks to limit Plaintiffs' evidence of pain and suffering, arguing that, under Tennessee law, Plaintiff Konrad's cannot be based on speculation and that, under Oregon law, Plaintiff Mitchell's damages may not include "loss of enjoyment of life." The motion should be denied in both respects.

As to Plaintiff Konrad, the jury is competent to determine the amount, if any, to award to Plaintiff for future pain and suffering based on whatever evidence of his damages the Court permits to be heard. As AbbVie correctly points out, "[e]vidence to support a claim for damages need only prove the amount of damages with reasonable certainty." *Overstreet v. Shoney's, Inc.*, 4 S.W. 3d 694, 703 (Tenn. Ct. App. 1999). "[U]ncertain or speculative damages are prohibited only when the existence, not the amount, of damages is uncertain." *Id.* Tennessee courts allow the jury compute damages for future pain and suffering. *See Cortazzo v. Blackburn*, 912 S.W. 2d 735, 741 (Tenn. Ct. App. 1995). Moreover, expert testimony is not required to support a jury instruction on future pain and suffering, when the injury is of an objective nature. *See Maddox v. Rozek*, 639 N.E. 2d 164, 166 (Ill. App. Ct. 1994) (collecting cases). Plaintiff Konrad does not seek to introduce speculative evidence and should not be limited in the type of *factual* evidence he can present to support his claims.

As to Plaintiff Mitchell, contrary to AbbVie's suggestion, Oregon law does not foreclose recovery for the "loss of enjoyment of life." In fact, the very case AbbVie cites merely found that "loss of enjoyment of life" is not a separate claim but nonetheless is a recognized component of pain and suffering. *See Ferren v. Nat'l R.R. Passenger Corpo.,* No. 00 C 2262, 2001 WL 1607586, at *8 (N.D. Ill. Dec. 12, 2001). ("[T]he Court will grant defendant's motion *in limine* insofar as it seeks to bar plaintiff from offering evidence or argument that the claims for … **loss of enjoyment** and vitality … are separate claims. However, **the motion is denied insofar as** it seeks to bar the

plaintiff from offering evidence and argument that his **pain and suffering damages include those items**.") (emphasis added). AbbVie's challenge should be rejected and the motion denied.

D. Testimony That a Doctor "Smashed" a "Trash Can" on Mitchell's Chest

AbbVie's motion correctly points outthat Plaintiff's wife testified during her deposition that Dr. Juliano "smashed" a "garbage can" on her husband's chest in the course of treating his heart attack. AbbVie then misleadingly cites to Dr. Juliano's testimony but does not reveal the details of his actual testimony. In fact, Dr. Juliano testified that he used an insulated plastic box, leaned on it, and pushed it to compress Plaintiff's chest to get the defibrillator's electrical leads closer to the heart while other hospital staff administered the electrical shock. *See* Excerpts of Deposition of Dr. Juliano (Juliano Dep.), attached hereto as Exhibit 32, at 25:11-21. AbbVie's argument gives the impression that Plaintiff's wife simply made up a story about her husband's treatment, which is simply not accurate. "Smash" may have been an inapt descriptor, and the item may not have been a "garbage can," but Dr. Juliano's testimony makes clear that the incident occurred. Plaintiff's wife's testimony is relevant to her husband's injuries and damages and is in no way unfairly prejudicial. *See* Fed. R. Evid. 403. This frivolous motion should be rejected out of hand.

May 18, 2017

Respectfully submitted,

/s/ Trent B. Miracle

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210

Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
Email: rjohnson@pschacter.com

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: cseeger@seegerweiss.com

Plaintiffs' Co-Lead Counsel *on behalf of* Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Brendan A. Smith
Brendan A. Smith
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: bsmith@simmonsfirm.com